



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2021-C-0787]

Piotrovska, PTY LTD.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Australian Laboratory Services, PTY LTD., on behalf of Piotrovska, PTY LTD., proposing that the color additive regulations be amended to expand the permitted uses of synthetic iron oxide as a color additive to include use in edible decorative paint.

DATES: The color additive petition was filed on June 28, 2021.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this document into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2710; or Jessica Larkin, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 721(d)(1) (21 U.S.C. 379e(d)(1))), we are giving notice that we have filed a color additive petition (CAP 1C0321), submitted by Australian Laboratory Services, PTY LTD., on behalf of Piotrovska, PTY LTD., Australian Laboratory Services, PTY LTD., 2-8 South Street

Unit 10, Rydalmere, NSW, 2116, Australia. The petition proposes to amend the color additive regulations at 21 CFR 73.200, a color additive regulation in 21 CFR part 73, “Listing of Color Additives Exempt From Certification”) by expanding the permitted uses of synthetic iron oxide as a color additive to include use in edible decorative paint.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(k) because the substance is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist that would warrant an environmental assessment (see 21 CFR 25.21). If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: August 13, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy

[FR Doc. 2021-17770 Filed: 8/19/2021 8:45 am; Publication Date: 8/20/2021]